Initial REMS Approval: 1/2013

Most Recent Modification: 06/2014

NDA 203098 Testosterone Gel, CIII

Drug Class and Formulation: Testosterone Gel Products

Perrigo Israel Pharmaceuticals Ltd.

Industrial Zone

Yeruham, Israel 80500

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(s):

To inform patients about the serious risks associated with the use of testosterone gel.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each testosterone gel, prescription in accordance with 21 CFR § 208.24.

The Medication Guide is appended.

B. Timetable for Submission of Assessments

Perrigo Israel Pharmaceuticals Ltd. will submit REMS assessments to FDA 18 months, 3 years and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment.

Perrigo Israel Pharmaceuticals Ltd. will submit each assessment so that it will be received by FDA on or before the due date.

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/s/

CHRISTINE P NGUYEN
06/19/2014